

Global pharma looks to India: Prospects for growth

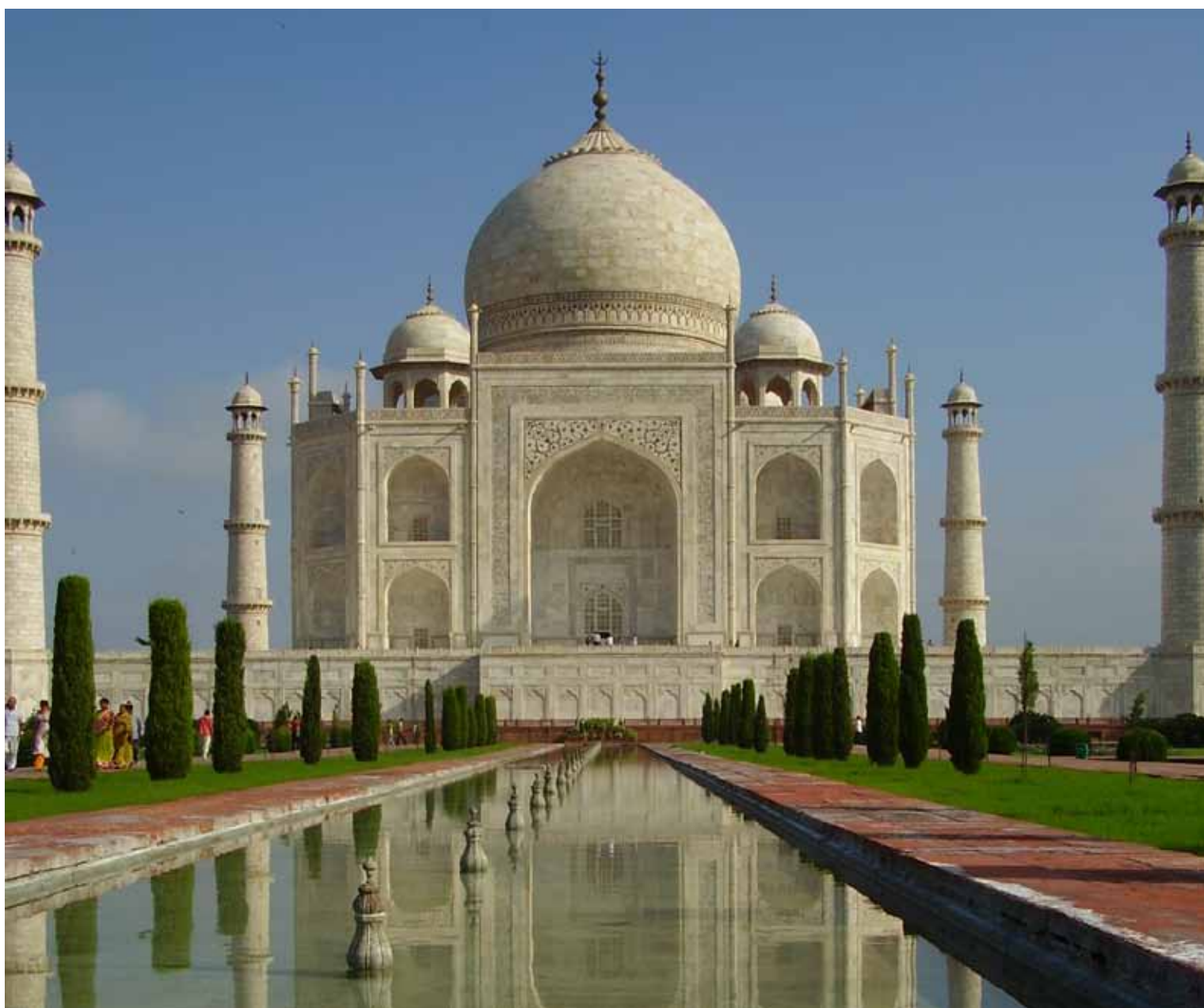


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Introduction

The pharmaceutical industry's main markets are under serious pressure. North America, Europe and Japan jointly account for 82% of audited and unaudited drug sales; total sales reached US\$773 billion in 2008, according to IMS Health. Annual growth in the European Union (EU) has slowed to 5.8%, and sales are increasing at an even more sluggish rate in Japan (2.1%) and North America (1.4%).¹ Impending policy changes, promoting the use of generics in these key markets are expected to further dent the top- and bottom-line of global pharma majors. The industry is bracing itself for some fundamental changes in the marketplace and is looking at newer ways to drive growth.

Further, higher R&D costs, a relatively dry pipeline for new drugs, increasing pressure from payers and providers for reduced healthcare costs and a host of other factors are putting pressure on the global pharmaceutical companies. Pharma companies are looking for new ways to boost drug discovery potential, reduce time to market and squeeze costs along the whole value chain.

How can industry leaders best face these challenges? Analysis by PricewaterhouseCoopers (PwC) shows that several regions offer considerable

promise, either as places with untapped demand for effective drugs or as suitable areas for conducting research and development (R&D) and/or clinical trials. In this paper we shall examine the opportunities available in India.

India's population is growing rapidly, as is its economy – creating a large middle class with the resources to afford Western medicines. Further, India's epidemiological profile is changing, so demand is likely to increase for drugs for cardio-vascular problems, disorders of the central nervous system and other chronic diseases. Together these factors mean that India represents a promising potential market for global pharmaceutical manufacturers.

More than that, India has a growing pharmaceutical industry of its own. It is likely to become a competitor of global pharma in some key areas, and a potential partner in others. India has considerable manufacturing expertise; Indian companies are among the world leaders in the production of generics and vaccines. As both of these areas become more important, Indian producers are likely to take a large role on the world stage – and potentially partner with global pharma companies to market their wares outside of India.

Indian companies have also started entering into the realm of R&D; some of the leading local producers have now started conducting original research. India has the world's second biggest pool of English speakers and a strong system of higher education, so it should be well-positioned to serve as a source for research talent. A new patent regime provides better protection of intellectual property rights, although some issues remain. Clinical trials can also be conducted here much more cost-effectively than in many developed nations, and some local companies are beginning to develop the required expertise. All of these factors add up to a strong case for partnering with Indian companies around R&D, including clinical testing.

Further, healthcare has become one of the key priorities of the Indian Government and it has launched new policies and programmes to boost local access and affordability to quality healthcare.

Global players in the pharma industry cannot afford to ignore India. The country, many predict, will be the most populous in the world by 2050. India will make its mark as a growing market, potential competitor or partner in manufacturing and R&D, and as a location for clinical trials.

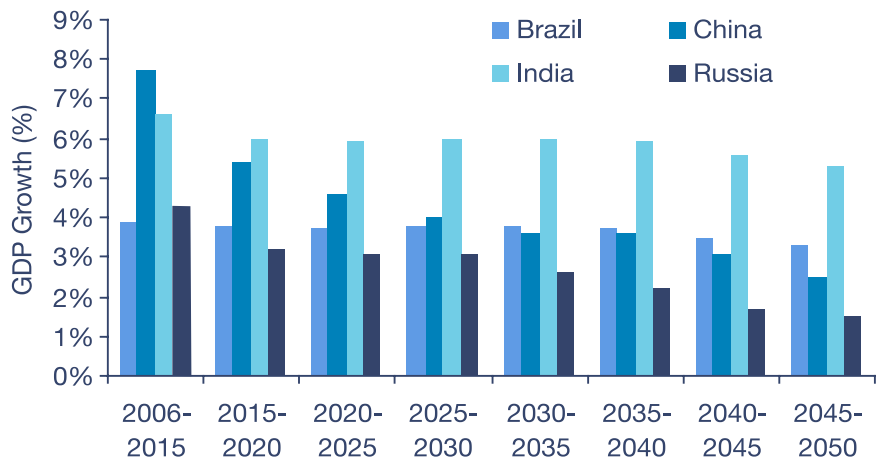
Background

A fast growing economy

The Indian economy is worth about US\$1,243 billion and rapidly getting bigger.² Real GDP growth reached 9% in the year to March 2008.³ The rate of increase has since slowed down due to the global financial crisis; in the year to March 2009, growth eased to 6.7%.⁴ Even so, most forecasters believe that India will continue to show robust growth over the long-term; a survey of professional forecasters performed for the Reserve Bank of India (RBI) anticipates growth improving to 6% in the year ending March 2010,⁵ and expects robust growth of 7.8% p.a for the next ten years.⁶ Previous forecasts such as those of Goldman Sachs suggest that India will be the only emerging economy to maintain such an outstanding pace over the longer term, i.e. to 2050 (see Figure 1).⁷

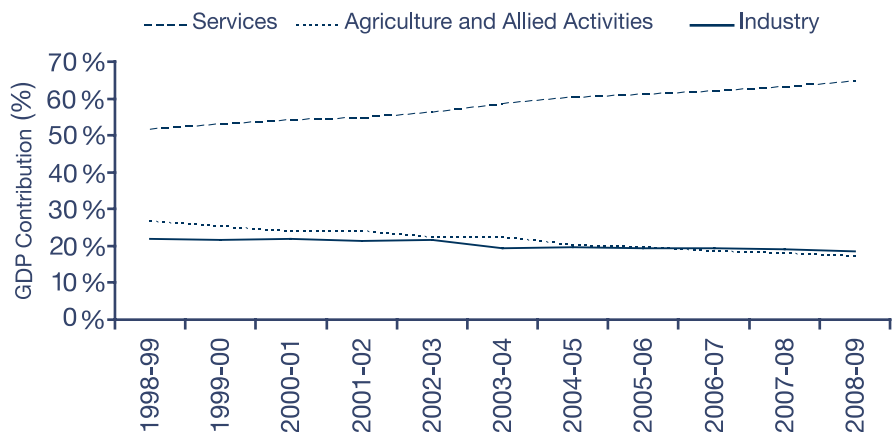
Two factors underlie this favourable outlook: India's demographic profile and a robust services sector. India's population is currently just over 1.1 billion and projected to rise to 1.6 billion by 2050 – a 45.5% increase that will see it outstrip China as the world's most populous state.⁸ India has also utilised its strengths in IT to become a major offshore business services provider, in marked contrast with most of Asia, which has relied on manufacturing for its recent growth. As a result, services now account for 64.5% of India's GDP (see Figure 2).⁹ While a strong services sector heralds well for continued economic prosperity, it also suggests why India looks to be important for research and development as well as drug manufacture; the country's experience delivering on outsourcing opportunities in other knowledge-critical areas such as IT should serve it well in its bid to offer such services in pharma, biotech and related areas.

Figure 1: India is forecast to grow by at least 5% a year for the next 41 years



Source: BRICs and Beyond, Goldman Sachs, November 2007.

Figure 2: India is shifting from agriculture to services



Source: Reserve Bank of India Annual Reports.

An expanding pharmaceuticals market

India's pharmaceuticals industry looks set for a solid long-term growth. It already ranks fourteenth in the global league table, with sales of almost US\$19 billion in March 2009.¹⁰ However, PwC estimates that it will rise to approximately US\$50 billion by 2020 – a 163% in the space of eleven years.¹¹ Indeed, in our report, *Pharma 2020: The vision*, we anticipate that India will be one of the industry's top 10 markets by 2020.

This growth will be driven by the expanding economy and increasing per capita GDP. In 2008, India's middle class constituted 13% of the population, according to the National Council of Applied Economic Research.¹² While this remains a fairly small proportion of the total population, it represents a substantial increase from a mere 3% in 1995.¹³ If the economy continues to grow faster than those of the developed world and the literacy rate keeps rising, around a third of the population (34%) is expected to join the middle class in the near future.¹⁴ While these consumers still earn substantially less than their US or European counterparts, they are rapidly acquiring the buying power necessary to afford modern healthcare, particularly if purchasing power parity is considered. One source estimates that at least 60 million Indians – a market as big as the UK – can already afford to buy Western medicines.¹⁵ Aggressive pricing strategies will be necessary, however, to make in-roads into India's price-sensitive market.

India's federal Government currently mandates price controls on essential drugs, however, these are under review. Price controls are carried out on certain drugs by virtue of the Drugs Price

Control Order (DPCO), supervised by the National Pharmaceutical Pricing Authority (NPPA). The 347 price-controlled drugs included in 1979 were reduced to 143 in 1987.¹⁶ At present, 74 bulk drugs are covered under the DPCO.¹⁷ The Government's draft pharmaceutical policy in 2006 sought to expand the scope of essential drugs and evoked a sharp reaction from the industry. They argued that it would adversely affect R&D activities in India, as companies would stay away from investing in new drugs. To date, no further action on the proposed policy changes have been taken and it currently looks unlikely that the DPCO will be expanded.

The Indian Government's Department of Pharmaceuticals has also initiated operations for a peoples' medicines shop, called 'Jan Aushadhi,' in various locations. These shops sell generic medicines at much cheaper rates than the price of corresponding branded medicines.¹⁸

Some multinational pharma companies are already taking measures to reach a larger patient population by reducing drug prices and increasing affordability. One example: Merck & Co. has launched differential pricing through Januvia, its anti-diabetic drug, which is priced at approximately US\$1 per dose in India – a fifth of its price in the US.¹⁹ Indian companies like Biocon have also followed a similar pricing strategy. Biocon has launched its monoclonal antibody BIOMAb EGFR at one-fourth of its price in the global markets.²⁰

It's also likely that India will require different types of drugs in the future. Like almost every other emerging economy, India is experiencing epidemiological changes. Thanks to greater affluence and better hygiene,

The bottom line: Increased buying power and epidemiological changes should spur dramatic growth in sales volumes, but India remains a price-sensitive market.

India's insulin dependence

The number of Indians with diabetes is projected to reach 73.5 million in 2025. The direct and indirect costs of treating such patients are currently about US\$420 per person per year. If these costs remained the same as they are now, India's total bill for diabetes would be about US\$30 billion by 2025. But as its economic wealth grows and standards of care improve, treatment costs are likely to rise.

The US spends an average US\$10,844 per year on each patient with diabetes. If India's per capita expenditure rose to just one-tenth of this level, the total cost of treating all patients with diabetes would be US\$79.7 billion by 2025. The value of prophylaxis in India alone would thus be substantial; preventing 10% of the population from developing diabetes would save nearly US\$8 billion a year.

Source: PricewaterhouseCoopers, *Pharma 2020: The vision*

the population is ageing; by 2028, an estimated 199 million Indians will be 60 or older, up from about 91 million in 2008.²¹ Besides that, it has the largest pool of diabetic patients, for example, with more than 41 million people suffering from the disease (see sidebar on India's insulin dependence).²²

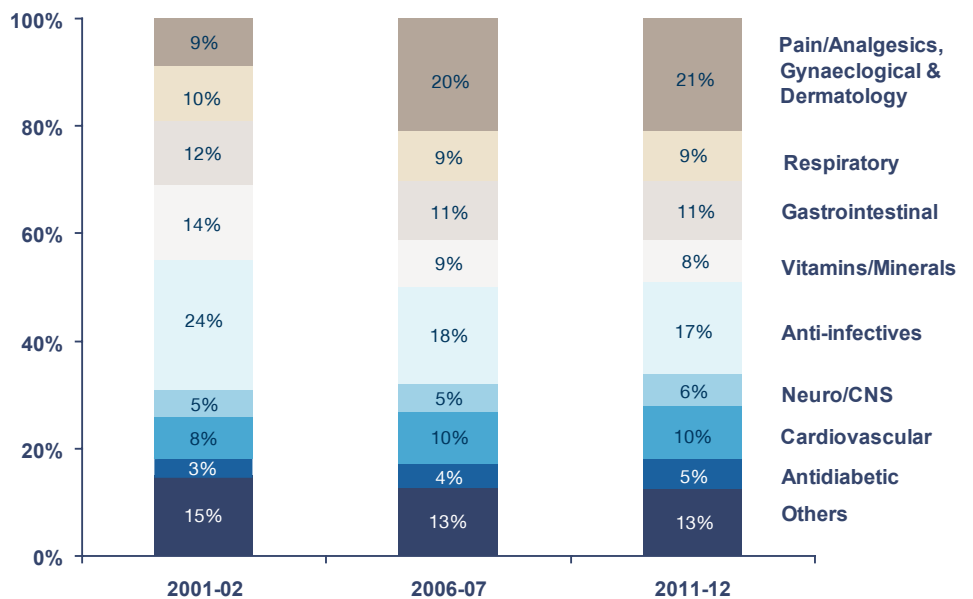
The pattern of demand for medicines is shifting accordingly. In 2001, anti-infective and gastrointestinal drugs and vitamins accounted for 50% of the domestic market. By 2012, they are expected to account for just 36%. Conversely, drugs for cardio-vascular problems, disorders of the central nervous system and other chronic diseases will account for 64% of total sales, up from 50% in 2001 (see Figure 3).

These factors help to explain why India is expected to be among the top markets for many pharmaceutical companies. It currently represents

about 8% of the global drugs market by volume and only around 1% by value,²³ but the Indian consumer's rapidly increasing purchasing power and the country's changing epidemiological profile could jointly improve its price/volume mix.

In order to get drugs to consumers at the right price, though, improvements to local supply chains will need to take place. One source estimates that logistics comprise 45-55% of the costs in the Indian pharmaceutical supply chain from factory to shelf.²⁴ India has historically had a pharma supply chain with a number of stops between the initial production and final consumer. The arrival of Goods and Services Tax (GST) may prove to be a strong incentive for greater streamlining, as such middle men could potentially add substantially to the final cost of medications in a price-sensitive market. Further, the consolidation of the pharma

Figure 3: India's therapeutic needs are changing



Source: ORGIMS Data, Crisil Research, Pharmaceuticals: Review Indian formulation market (2008)

industry and emergence of pharma retail chains are likely to lead to more concentration in the supply chain. The increasing requirements posed by some formulations like biologics, which require advanced expertise such as the ability to maintain the cold chain and avoid shocks during the distribution process, will also play a role. Inventory reduction and the reduction of order cycle time will be key objectives for companies looking to optimise their supply chains in order to offer their drugs at affordable prices.²⁵

Government-provided healthcare improving, but private healthcare dominates

The Indian Government is currently in the throes of a much needed programme to reform the health care system. After years of under-funding, most public health facilities provide only basic care. Moreover, three quarters of medical facilities are located in urban areas, leaving the majority of rural

workers without access to hospitals or pharmacies (**see Table 1**).²⁶ Many of the poor rely exclusively on alternative forms of treatment such as Ayurvedic medicine²⁷, Unani²⁸ and Acupuncture.

The Indian Government has made the provision of healthcare as one of its

Table 1: India healthcare facilities

Doctors	60 per 100,000 people ²⁹
Nurses	80 per 100,000 people ³⁰
Pharmacies	367,000 (urban), 183,000 (rural) ³¹
Hospitals	30,000 (67% public, 23% private) ³²
Hospital beds	1.7 million (one per 1,000 people) ³³
Health centers	171,687 (including 145,272 sub-centres with basic facilities) ³⁴

Sources: World Health Organisation (2008) Modern Pharmaceuticals (December 2008); Health System in India: Opportunities and Challenges for Improvement (July 2005) Expresspharmaonline.com (2007); and World Health Organisation (2007).

The bottom line: India's healthcare system is struggling to meet the needs of its vast population, but government programmes and reforms in the health insurance industry should improve the situation.



key priorities. It launched a new policy to build more hospitals, boost local access to healthcare and improve the quality of medical training, and promised to increase public expenditure on healthcare to 2-3% of GDP, up from a current low of 1%.³⁵ The 2008-09 Union Budget highlighted a five year tax holiday for setting up hospitals anywhere in India, especially in tier-2 and tier-3 towns.³⁶ The Government further allocated US\$51 million for a new health insurance scheme to provide a health cover of US\$745 for every worker (including his/her family) in the unorganised sector falling below poverty line (BPL),³⁷ which was increased to US\$76 million in 2009-10 budget.³⁸ The recent budget (2010-11) extended the coverage to another 20% of the Indian population covered by the NREGA (National Rural employment Guarantee Act) programme, who have worked for more than 15 days during the preceding financial year.³⁹ Budget

2010-11 also allocated US\$ 2,920 million under the National Rural Health Mission (NRHM), an increase of 15% over the previous year.⁴⁰

However, critics suggest that the authorities are doing too little too late, and those who can afford it have turned to the private sector instead. In 2008, fee-charging private companies accounted for 80% of India's US\$48.6 billion expenditure on healthcare, while central and local Government accounted for only around 20%. Private firms are now thought to provide about 80% of all outpatient care and as much as 55% of all in-patient care.⁴¹

Some costs for care may be covered by the insurance industry in the future, although the current lack of general coverage remains a challenge. In 2007, only 11% of the population had any form of health insurance coverage. For the small percentage of Indians

who do have some insurance, the main provider is the Government-run General Insurance Company (GIC), along with its four subsidiaries, but private insurance is on the rise. The health insurance market in India has undergone liberalisation in recent years. Further, the Insurance Regulatory and Development Authority (IRDA) eliminated tariffs on general insurance as of January 1, 2007, and sales have been going up accordingly. In 2007-08, almost US\$1.2 billion worth of medical insurance policies were sold in India – up from US\$160 million in 2001-02.⁴² But widespread use of health insurance could take many years, not least because the insurance companies lack the data they require to assess health risks accurately and the only products they sell work on an indemnity basis – that is, they reimburse the patient after he or she has paid the healthcare provider's bill, making such policies less attractive.



Domestic market overview

Background

India's domestic pharmaceutical industry was worth around US\$11 billion in March 2009 and PwC estimates it will rise to approximately US\$30 billion by 2020.⁴³ The domestic market is very fragmented; more than 10,000 firms collectively control about 70% of the market.⁴⁴ Many of the local players are generics producers specialising in anti-infectives. In 1972, the federal Government passed a law allowing local producers to manufacture drugs that were still under patent, as long as they used different processes.⁴⁵ The lack of a patent system that conformed to international standards helped spawn a domestic industry that excelled in reverse engineering novel drugs and launching copycat versions at home and in other emerging markets. Wholesale marketing of generic versions of drugs patented since 1995 and still under patent has not been permitted since

2005 (see **Intellectual Property Rights on page 29**), so market strategies are changing and some generics producers are looking further afield for new markets.

India's manufacturing clout has made it a massive threat to established generics firms – India now produces more than 20% of the world's generics.⁴⁶ Moreover, around US\$70 billion worth of drugs are expected to go off patent in the US over the next three years, and India is well-positioned to take a substantial share of the resulting new generics markets.⁴⁷ Indian companies today account for 35% of the Abbreviated New Drug Application (ANDA) approvals granted by the US Food and Drug Administration (FDA) until February 2009.⁴⁸ India's generic houses are now entering into strategic alliances with global pharma companies to strengthen their generic portfolio and jointly market these drugs globally,

The bottom line: 2008 saw M&A in the pharma sector in India more than double against the previous year, despite the challenges posed by the global recession.



for example Pfizer has entered into alliances with Aurobindo and Claris to market their drugs in offshore markets. Similarly, GlaxoSmithKline (GSK) has acquired exclusive rights for Dr. Reddy's Laboratories' (DRL) pipeline of over 100 generics for sale in emerging markets. In addition to partnering with global pharma, some Indian companies are also setting up their own marketing subsidiaries abroad.

India's pharmaceutical exports totalled around US\$8 billion in 2009 and PwC estimates they will rise to approximately US\$20 billion by 2020.⁴⁹ Over the past several years companies such as DRL, Cipla and Lupin have grown internationally in their own right as well. Other Indian pharma companies like Glenmark Pharma, Orchid and Aurobindo also have wholly owned subsidiaries in different parts of the globe.

DRL has grown from a small firm into an international business with annual sales of more than US\$1.4 billion, about 84% of them outside India.⁵⁰ The company's acquisition of Germany's Betapharm positioned it as one of the largest generics companies in the world; it is currently one of the largest suppliers of drugs to the US. It is also one of the

largest active pharmaceutical ingredient (API) manufacturers globally.

Cipla is another company with revenues of over US\$1.1 billion, 56% of which come from outside India.⁵¹ It is one of the largest manufacturers of antiretroviral drugs in the World.⁵² In 2007, an Avesta-Cipla joint venture acquired Siegfried Biologics, a Switzerland based company, to manufacture US FDA and European Medicines Agency (EMA) compliant biopharmaceuticals for the global markets.⁵³ Meanwhile, Lupin is the biggest producer of Lisinopril, an API used in the treatment of hypertension.⁵⁴ Lupin's acquisition of Multicare Pharmaceuticals of Philippines has propelled it into position as a top generics player in the Philippines.⁵⁵ The deal represented Lupin's sixth acquisition since 2008.

Consolidation underway, despite challenges

The Indian pharma industry as a whole is moving on a consolidation path. The year 2008 saw 57 mergers and acquisitions,⁵⁶ a 128% increase over the previous year.⁵⁷ Total investment in pharmaceutical, healthcare and biotechnology sectors

was second among industry sectors in terms of deal value at US\$5.57 billion, marginally below the Telecommunication sector which had total transactions worth US\$5.78 billion in 2008. In the same year, India's largest pharma company, Ranbaxy Laboratories, was acquired by Japan's Daiichi Sankyo. This was a landmark deal in the Indian pharma history, where Ranbaxy's promoters relinquished their entire stake to the acquirers. The transaction paved the way for other promoters to consider whether they are better served growing their businesses independently or by realigning with other partners who may be able to help them to take their businesses to the next level of growth.

In 2008, the world went through a credit crunch, followed by a prolonged global economic downturn in the last quarter of 2008 and throughout 2009, both of which have also had a negative impact on the Indian pharma industry. The impact of the downturn, coupled with volatility in the Rupee, depleted the financial position of several Indian pharma companies, especially those which had substantial foreign borrowings on their balance sheets.

Sustaining acquisition heavy structures became increasingly difficult in 2008.



Some Indian companies which made significant acquisitions were now finding it difficult to integrate their foreign acquisitions with the Indian operations due to severe pricing pressures. Legislative reforms imposed in acquisitions' home markets also had an impact. Further, some companies booked losses on foreign currency convertible bonds (FCCBs), negatively impacting overall profitability.

Nonetheless, investor confidence has remained fairly stable and deals continue despite challenges. The average deal size in 2008 was around US\$15.34 million, 20% higher than US\$12.82 million in 2007. The pharma sector had 57 deals, of which 17 deals were domestic. There were a total of 22 pharma private equity (PE) deals worth US\$337.41 million. Private equity players and investment funds played an active role in the deal market. Some of the investments were those of Citi Venture and Everest Capital of about US\$23.6 million in Nectar Lifesciences.⁵⁸ Similarly, Kotak Private Equity Group, an arm of Kotak Mahindra Bank, invested about US\$10 million in Intas Biopharmaceuticals.⁵⁹ Gujarat Biotech Venture Fund invested US\$12.7 million in Century Pharmaceuticals and SME Growth Fund invested US\$7 million in Centaur Group.⁶⁰

Further, in 2009 another landmark deal was announced, with sanofi-aventis acquiring controlling stakes in the leading Indian vaccine manufacturer Shanta Biotech.

Elsewhere we discuss some of the strategies that Indian companies employed to stay afloat during the crisis, including greater focus on leveraging their strengths in newer structures like Contract Research & Manufacturing Services (CRAMS), biotech & clinical trials, and increasing penetration in rural markets.

Contract manufacturing

Contract manufacturing is a strong segment of the domestic market. Indian firms have several advantages over their Western rivals. The expertise gained in manufacturing generics through reverse-engineering has helped some companies streamline the process for getting manufacturing up and running. Costs are very competitive; indeed, they are only two-fifths of those involved in setting up and running a new manufacturing facility in the West.⁶¹ They can operate on significantly lower margins, given their low development and labour costs. Currently their key area of strength in

The bottom line: 2008 saw M&A in the pharma sector in India more than double against the previous year, despite the challenges posed by the global recession.



The bottom line: Indian pharma companies have solid expertise in contract manufacturing and recent scrutiny around quality issues is driving significant improvement in manufacturing standards.

outsourcing is the manufacture of APIs. Some Indian pharma companies could probably benefit significantly by moving towards specialty APIs in the future.

The Indian contract manufacturing segment was worth around US\$605 million in 2008 and is expected to reach around US\$916 million in 2010.⁶² The US FDA has already approved over 100 manufacturing sites – more than in any country except the US (see **Figure 4**).⁶³ Among six offices that the US FDA has overseas, two are located in India, in Delhi and Mumbai.⁶⁴ All domestic producers are also obliged to comply with India's Good Manufacturing Practices, under Schedule M of the Drugs and Cosmetics Act, 1940.

Indian manufacturers are currently facing some scrutiny around quality issues. In 2009, the US FDA took action against a few Indian companies after conducting a series of inspections and issuing warning letters against these drug makers.

While such sanctions clearly pose significant challenges, some analysts see an opportunity as well. Indian companies are aggressively improving their manufacturing standards in response, and are therefore likely to be better positioned to take advantage of the upsurge in generics production

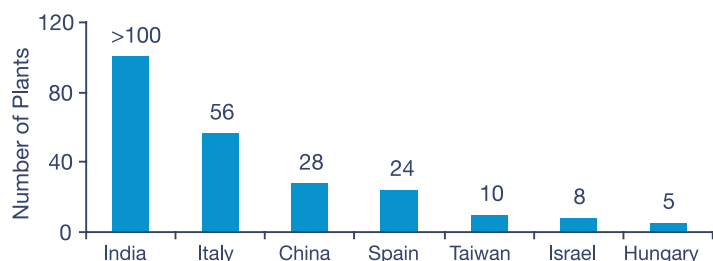
expected as patents expire over the next five years.⁶⁵

Some Indian manufacturers are also now incorporating Lean Manufacturing and Six Sigma principles to help them boost operational efficiency and further improve quality, while facilitating compliance.⁶⁶

Vaccines

Vaccines are another prominent area of growth. India is one of the largest vaccine producers in the world, with many new vaccines set to be launched in the next five years. The vaccines segment was around US\$780 million in March 2008, growing at a compounded annual growth rate (CAGR) of 15%.⁶⁷ India currently exports vaccines to about 150 countries. It also meets around 40-70% of the World Health Organisation (WHO) demand for the DPT (diphtheria, pertussis or whooping cough, and tetanus) and the BCG (bacille calmette-guérin) vaccine against tuberculosis, and almost 90% of its demand for the measles vaccine.⁶⁸ The Serum Institute of India, founded in 1966, is a leading player which produces and supplies low-cost, life-saving vaccines for children and adults. The Institute is also the world's largest producer of measles and DPT vaccines.

Figure 4: India has more US FDA-approved manufacturing plants than any country except the US



Source: Crisil Research, Bulk drug exports to scale up in the regulated markets (December 2008) for India; ICICI Securities, Indian Pharma Sector: Sector Update (December 2008) for Italy, China, Spain, Taiwan, Israel and Hungary.

It has been commissioned by the WHO to develop vaccines against the latest strain of H1N1. An estimated two out of every three immunised children in the world have received a vaccine manufactured by the Serum Institute.⁶⁹ As the risk of global pandemics grows, so do potential markets for new vaccines.

OTC market holds significant potential

Globally, over-the-counter (OTC) drug sales have been increasing in recent years. This trend is driven in part by aggressive efforts of global pharma companies to leverage the brand equity that major products have attained during the patent period. Other major winners in the OTC category include products where patients continue to buy particular remedies following an initial doctor's prescription.

OTC drugs may have even stronger potential in India. An increasing number of Indians are already dipping into their own pockets to buy OTC drugs. The OTC market was worth about US\$1.8 billion in 2009 and is expected to grow at 18% a year to reach about US\$3 billion in 2012.⁷⁰ The Government is now considering plans to expand the list of drugs which can be sold outside pharmacies, since many common household remedies are more difficult to obtain in India than in other developing countries. An expansion of the list would substantially increase the potential market opportunity in this segment.

Although the term 'OTC' has no legal recognition, all the drugs that are not included in the list of 'prescription only drugs' are considered as non-

prescription drugs (or OTC drugs). OTC proprietary drugs are also regulated by the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules. However, as they do not require a drug license they can be sold by non-chemists, so sales channels are more extensive. As discussed, much of India's population relies on self-medication, and the purchasing power of the middle class is growing. These trends should drive growth in cough and cold formulations, gastrointestinals, analgesics, and dermatologicals. Only a few OTC active ingredients, e.g. acetylsalicylic acid and ephedrine and its salts, fall under the current DPCO price control. Counterfeits of popular OTC drugs are however a major issue.

Indian consumers are also placing more emphasis on prevention and wellness, which should contribute to continued increases in sales of OTC vitamins and minerals. The market is already growing strongly. Profitable OTC drugs for some of India's largest pharma companies include artificial sweeteners, emergency contraceptive pills and nutritional supplements.

The popularity of Ayurvedic therapies should also contribute to the sales of related OTC formulations. Some of the leading OTC brands in India are registered as 'Ayurvedic Medicines' because of their plant-based natural active ingredients. There are no price controls on 'Ayurvedic Medicines'.

Some global pharma companies are already launching OTC products in India or buying OTC products. Novartis India launched Calcium Sandoz as an OTC supplement in 2000 and has now come out with Otrivin nasal drops in a spray form.⁷¹ Pfizer has launched Listerine, Benadryl, Caladryl and Benylin in India,

The bottom line:
OTC sales
are on the
increase, offering
opportunities
to achieve high
volumes and
enhance pharma
brands in India.

The bottom line: While urban markets will remain the focus in the near-term, getting treatment out to the 70% of the population residing outside of these areas represents the next volume driver.

which were later sold to Johnson and Johnson.⁷² In the future, India may also serve as a manufacturing location for OTC products destined for other markets. In August 2009, US-based OTC manufacturer Perrigo announced the purchase of 85% of Indian contract manufacturer Vedants. The company plans to shift some of its current production from facilities in Israel and Germany to India by 2011.

India's regulatory framework permits advertising for OTC products, and consumers can buy them without a doctor's prescription. However, a wider distribution network will also boost the growth of such products. Currently about half of OTC sales come from chemists, while grocery stores and general stores account for over a third of the sales.⁷³ Pharma companies are also targeting post offices to sell OTC drugs in rural India. This move could substantially increase the access of OTC drugs, especially in areas where there are no pharmacies.

Reaching the untapped rural market

Although urbanisation continues, around 70% of India's population still resides in rural areas. As already noted, the population residing in villages has significantly reduced access to quality treatment and medicines. Many pharma companies are thinking beyond larger cities and targeting rural sectors. While urban markets are currently

more lucrative and will continue to represent a focus for the industry, the untapped potential of Indian rural markets is now seen as the next volume driver. Rising income levels leading to more affordability, improving health infrastructure, and increasing incidence of lifestyle diseases along with the use of health insurance are fuelling the growth in rural areas.

Indian companies are devising a number of strategies to increase rural penetration. For instance, Lupin has a strong brand franchise in the anti-infective, pain management, and gastrointestinal segments – these three areas account for 40% of domestic formulations sales. The company has a dedicated rural field force of more than 300 people and is rapidly expanding it. Piramal Healthcare has also announced a new initiative to target the mass market, focused on general practitioners, to cater to rural markets. Piramal plans to employ a field-force of approximately 800 people.

Companies looking to access rural markets face many hurdles, including lack of communication, language barriers, high penetration of spurious drugs, lack of adequate infrastructure, such as marketing and distribution channels for niche therapeutic segments in particular, poor storage facilities, and insufficient sales personnel deployment. Global pharma companies eyeing rural markets will need to forge alliances and partnerships to overcome these obstacles.

Growing Research & Development

Overview

PwC estimates that India's 10 largest drug firms spent US\$480 million on R&D in 2008. The bulk of this investment went towards developing new formulations, however R&D in the Indian pharmaceuticals industry is changing. The new patent regime means companies need to be more innovative, rather than relying solely on reverse-engineering existing formulations. The reliance on anti-infectives is also likely to lessen. As already noted, as the illnesses of affluence and age increase, the demand for many other types of pharmaceuticals will rise, and Indian pharma companies need to begin transforming their portfolios accordingly.

India has widely acknowledged chemistry skills. Several leading domestic producers have begun to conduct original research into new chemical entities and novel drug delivery systems. Amongst others, Ranbaxy has commenced phase-III clinical trials for its new anti-malarial combination drug. Other companies are looking to shift to clinical areas with a growth opportunity, such as diabetes (see sidebar on India's insulin dependence on page 6). Piramal Life Sciences has initiated phase-I trials of a new experimental drug for diabetes-metabolic syndrome in Canada. DRL is conducting phase-III trials for its Type II diabetes drug. Other areas of innovation are also being explored; Biocon has 7 and Wockhardt has 10 new chemical entities in their R&D pipelines.

However India offers limited capabilities in preclinical and complex Biology research. Preclinical capabilities in India are limited to clinical trials in rodents and dogs, with almost none for primates. The capabilities mostly reside with Indian pharmaceutical companies, developed through in-house R&D programmes – Government involvement in this area is minimal. Some Government institutes do offer basic biology services, but the level of innovation generated by such facilities is fairly modest. Multinationals will need to partly/completely own or share technology with available Indian Contract Research Organisations (CROs) in order to achieve innovative results. The Indian contract research segment was estimated at around US\$485 million in 2008 and is expected to reach around US\$1 billion in 2010.⁷⁴

Despite Indian pharma companies' growing expertise in later stages of the R&D process, many of the drug candidates initially formulated in India are likely to be further developed by Western drug makers, because few Indian companies can afford the high costs and failure rates associated with pushing a drug right through the pipeline. Several Indian firms have already entered into research partnerships with multinationals; DRL and Torrent have joined forces with Novartis, for example, while Ranbaxy has formed alliances with GSK and Schwarz Pharmaceuticals. Glenmark has formed an alliance with Napo Pharmaceuticals and Piramal Healthcare

has formed an alliance with Eli Lilly. By selling developing and licensing rights for the US, Japan and Western Europe, but retaining rights within emerging markets, some Indian pharmaceutical companies are able to gain immediate revenues, while retaining future access to India's growing domestic market.

A number of Indian pharma companies have spun off their R&D divisions into separate units in order to scale up resources and to attract focused investments. DRL started the trend in R&D spin-offs in 2005. Piramal Life Sciences, Piramal Healthcare's R&D division, was recently demerged from the latter. Sun Pharma Advanced Research and Ranbaxy Life Science Research have also been demerged from their parent companies Sun Pharma and Ranbaxy respectively. Some spin offs have faced difficulties stemming from uncertain resources and declining PE interest in research. Several companies are now seeking a collaborative approach towards drug discovery, in order to mitigate the risk associated with failure of a drug molecule.

India's R&D base is still small, but it has several advantages that should serve it well in the future. Some 70 million people speak English⁷⁵ – more than in any other country except the US – and it has an excellent tertiary education system; every year, it turns out about 115,000 scientists with Master's degrees, and 12,000 with PhDs.⁷⁶ Many of these scientists have traditionally

gone abroad, but companies like Ranbaxy are now actively trying to lure them back with the prospect of opportunities for original research. Salaries are also very much lower than they are in North America or Western Europe. Wage costs within the Indian pharmaceutical industry are about one-third of those in developed countries.⁷⁷

To achieve its potential and convert these opportunities into global success stories, the Indian pharma industry requires the support and collaboration of all stakeholders, including the Government, academia and financial investors. Collaboration will be essential; but to date only a few Indian pharmaceutical companies have partnered with academic institutes to carry out basic research.⁷⁸ Such cooperations can help accelerate the research process in some areas. Partnering with academia can also help develop the sophisticated skills needed for high-level research. Pharma players who can leverage the research capability of academic and Government institutes, through mutually beneficial collaborative models, will gain significant competitive advantage.

Amongst emerging economies, India has the unique advantage of its recent

successes in the global software and IT services market. In this respect, India offers one of the very few examples of an emerging economy that has managed to attract Foreign Direct Investment (FDI) in the area of high-tech software development, while successfully inserting itself as a competitive presence in the very heart of Silicon Valley. Biotech, another knowledge-based sector, is now experiencing a similar boom. Drawing on the success of IT enterprise parks, the Government also inaugurated the first phase of its first biotech-IT park – Bangalore Helix in June 2007. The project is part of efforts to position India as a global hub for bioinformatics and biotech.

Clinical Trials

India's developing research skills are matched by its growing involvement in clinical testing. The country historically lacked the expertise to perform clinical trials because most companies only tested different processes for producing copycat versions of Western products and the rules were quite lenient. Several drug makers have also been caught behaving unethically or even illegally. The Supreme Court and Drug Controller General of India (DCGI) have criticised a

few India pharma companies for testing new drugs without getting patients' consent or for violating protocol. However, during the past few years a number of big contract research organisations have set up businesses in India, including Quintiles, Omnicare, PharmaNet and Pharm-Olam. Most of the multinationals, Novo Nordisk, sanofi-aventis, Novartis and GSK among them, have likewise started running clinical trials here – and some, such as Pfizer and Eli Lilly, have been conducting tests locally for a while.

In January 2005, the federal Government amended Schedule Y of the Drugs and Cosmetics Act to make the rules on clinical trials more consistent with international practice.⁷⁹ The Health Ministry is planning to add a new Schedule Y-1 to the Drugs and Cosmetic Rules 1945 to further improve the situation.⁸⁰ Early stage testing of molecules discovered outside India is still restricted, but multinationals can now conduct trials where, previously, they could only conduct trials in any particular phase after completing the same phase of testing elsewhere.⁸¹

At present, though, the industry still lacks a strong regulatory framework. Good Laboratory Practices (GLP) certification remains a voluntary

process, although most Indian pharma companies dealing with international clients or exporting to foreign regulated markets look to attain such certification. The National Good Laboratory Practice Compliance Monitoring Authority was established under the Department of Science and Technology in April 2002. While this was undoubtedly a step in the right direction, there are still only about 33 GLP inspectors⁸² and about 12 GLP certified labs in the country.⁸³ In addition, the ruling on whether a trial design violates ethical principles is left to individual local ethics committees. There is no central register of Ethical Committee decisions. Better infrastructure for regulation, ethics review and monitoring is required.⁸⁴

The Clinical Establishments (Registration and Regulation) Bill, 2007, which is yet to be approved, proposes compulsory registration of all clinical trial establishments subject to compliance with prescribed standards. The bill also calls for setting up a National Council entrusted with forming the standards required.⁸⁵

This type of more rigorous regulatory oversight, together with increasing interest from foreign firms, should help to boost the Indian clinical trials market. Expectations are already high; some

observers expect the market could reach US\$2 billion annually by 2012, up from just US\$300 million in 2008.⁸⁶ The strong anticipated growth reflects some of the attractions India holds for this market. According to a study by Rabo India Finance, a subsidiary of the Netherlands based Rabo Bank, the huge patient population offers vast genetic diversity, making the country “an ideal site for clinical trials.” Further, many people are “treatment-naïve” and relatively easy to access. The United Nations reports that around 30% of the population lives in urban areas;⁸⁷ and over 67 million people live in India’s six biggest cities alone (see Table 2).

The ratio of doctors to patients – at 60 per 100,000 people – is also

Table 2: Urban India

City	Population (Data in '000)	
	2005	2010
Bangalore	6,465	7,229
Kolkata (Calcutta)	14,282	15,577
Chennai (Madras)	6,918	7,559
Delhi	15,053	17,015
Hyderabad	6,117	6,761
Mumbai (Bombay)	18,202	20,072

Source: United Nations, World Urbanization Prospects (2007)

The bottom line: Insufficient regulatory oversight is currently a barrier, however India’s many advantages – overall costs are only 50% of comparable US-based programmes – should spur dramatic growth in clinical testing in the next 2-5 years.



relatively high, although the quality of medical training is not as good as it is in some other emerging nations. The country's 289 medical colleges are over subscribed and the emphasis is on quantity rather than quality.⁸⁸ These problems are compounded by lack of experience. India has only 500 to 1,000 investigators in the country as compared to 50,000 in the United States, suggesting that most companies would need to make a major investment in training during study start-ups.⁸⁹

Some Indian pharma companies are already developing a reputation for a nimble, rapid approach to clinical testing that looks to streamline the clinical trial process and bring new drugs to market faster. For example, Glenmark now routinely looks to incorporate "proof of mechanism" into every phase-I study.⁹⁰ Most pharma companies save this step for phase-II.

But the most obvious benefit of conducting clinical trials in India is the potential for cost savings. Clinical trials account for over 40% of the costs of developing a new drug.⁹¹ In terms of cost efficiency, India offers substantial advantages – the cost of conducting a trial here is lower by 50% than in the United States.⁹² The federal Government is alive to the strength of this argument. Drugs and materials imported for clinical trials are exempt from customs duties. Clinical trials also remain exempt from service tax.

Biotech and biosimilars on track for growth

India is home to a small biotechnology industry, based largely in Karnataka, with other clusters of activity in West Bengal, Maharashtra, Andhra Pradesh, Hyderabad, Kerala and Ahmedabad. In 2008-09, the sector generated sales of US\$2.64 billion⁹³ representing a CAGR of 26%, but both the federal and state Governments have been actively promoting biotech research initiatives and are targeting revenues of US\$5 billion by 2010 -11.⁹⁴ The leading domestic players include Serum Institute of India, which focuses on immuno-biologicals and vaccines; Biocon, which concentrates on recombinant DNA technologies, bioprocesses, fermentation-based small molecules and enzymes; and Panacea Biotec, which specialises in novel drug delivery techniques and pharmacogenomics (**see Table 3**).

Several initiatives have been launched by the Government to give impetus to the thriving biotech industry. The Biotechnology Industry Partnership Programme (BIPP) has been launched by the Department of Biotechnology (DBT) to support high-end biotechnology research programmes capable of generating globally recognised intellectual property. It specifically focuses on transformational research and development. The DBT has also drafted the National

Table 3: India's top 10 biotech firms

Company	Revenues (US\$ million) 2008-09
Serum Institute of India	242.12
Biocon	198.29
Panacea Biotec	129.79
Rasi Seeds	81.63
Nuziveedu Seeds	79.11
Novo Nordisk	71.72
Siro Clinpharm	60.86
Novozymes South Asia	54.34
Shantha Biotech	53.68
Jubilant	52.60

Source: Biospectrum – ABLE, 2009 ⁹⁵

Biotechnology Regulatory Act in order to set up the National Biotechnology Regulatory Authority (NBRA). The NBRA is expected to be an autonomous body formed specifically to regulate the biotechnology segment and reduce regulatory overlap.⁹⁶

Further funding support from the Government will be critical in ensuring continued growth in the biotech industry. The Government can play a vital role in funding incubation and early stage ventures.

A growing biotech industry should help India to gain a share of the global opportunity currently emerging around biosimilars. The biosimilars market is likely to grow by around US\$2 billion by 2014, to reach a total of US\$19.4

billion, following key patent expiration for epoetin alpha, filgrastim, interferon beta 1a, interferon alpha, human growth hormone (hGH), and insulin-glargine.⁹⁷ This represents a CARG of 89.1% from 2009 to 2014. All told, around US\$25 billion worth of biologics are expected to go off patent by 2016.⁹⁸ These patent expirations open the route for biosimilars, the equivalent of generics for biologics.

Indian biotech companies are slowly building capabilities in development and manufacturing of biosimilars. Intas Biopharmaceuticals is now developing a biosimilar of a protein used to treat the side effect of cancer therapy, for example.⁹⁹ Biocon has initiated registration of its human recombinant insulin with the European regulatory agency, EMEA and intends to launch it by 2011.¹⁰⁰ Reliance Life Sciences has launched three biosimilars—ReliPoietin (Erythropoietin), ReliGrast (GCSF), and ReliFeron (Interferon Alpha 2b) in the domestic market in 2008 and is currently conducting clinical studies for erythropoietin and granulocyte colony stimulating factor (GCSF) in Europe.¹⁰¹ Wockhardt has launched its recombinant erythropoietin, Wepox and insulin, Wosulin in the domestic market¹⁰² and is conducting clinical trials in the US for Wosulin.¹⁰³ It has built capacities in erythropoietin, hepatitis vaccine, recombinant insulin and insulin glargitus. DRL has already launched filgrastim and rituximab in emerging

markets and has a pipeline of 10 biogenerics in various stages.¹⁰⁴

The challenge for the development of biosimilars arises from the fact that biologics are more complex than small molecules and chemically synthesised drugs; therefore their replica are – in contrast to ‘traditional’ small-molecule generics – ‘similar’ but not identical to the original drug. Consequently, the registration of biosimilars requires more data than is required for generics, and manufacturers have to demonstrate efficacy and safety in pre-clinical and clinical studies. This makes the registration of biosimilars a costly and time-consuming process, and lessens the chances of a successful launch. Developing biosimilars is costlier than developing chemical based generics, requires a greater capital investment and operating costs of manufacturing are higher. These factors mean that developing biosimilars represents a higher risk area of R&D.

Pharma companies need to balance the risks and rewards when considering whether to enter the biosimilars market. The decision to enter the market should only be made based on a clearly defined long-term biosimilar strategy, including development and manufacturing capabilities, marketing, pricing and regulatory expertise. India’s cost advantages in many of these areas could help it gain a stronghold globally in this growing market.

The bottom line:
India’s developing
biotech industry
and cost
advantages
should drive
significant
growth in local
development of
biosimilars for the
global market.

Other growth areas

The bottom line: India's existing knowledge capital in IT provides a natural base for the development of bioinformatics research and operations.

Bioinformatics in India

The modern process for drug discovery and testing now generates very large quantities of data through computer modeling and simulations, genetic sequencing, and other data-intensive processes. Further, as we noted in *Pharma 2020: The vision*, pharma companies are under increasing pressure to document the efficacy of their products; tracking patient outcomes represents a further source of large quantities of data. In order to facilitate the storage, management, retrieval and analysis of this large pool of data, a new subsector of the IT sector has emerged – bioinformatics. Tools have been developed which can help lower cost, improve efficiency, and streamline the process of documenting a drug's efficacy throughout development until launch and beyond.

India's strength in the IT sector and its growing pharmaceutical sector are driving growth of this emerging area. Revenues for the Indian bioinformatics industry were around US\$48 million as of March 2009. It is an export driven segment with earnings of around US\$37 million from overseas. Domestic revenues contribute around US\$11 million.¹⁰⁵ Some companies provide only specialised bioinformatics services; in other cases, local life sciences companies are integrating bioinformatics services into a complete portfolio of research capabilities.

India is now actively targeting the bioinformatics market, with the construction of its first biotech-IT park in Bangalore, at a total cost of about US\$87 million.¹⁰⁶ The first phase of the park has been completed and a tender for the development for phase-II is expected soon from the local state Government. Several Indian companies, including the Bangalore based Strand Genomics and Ocimum Biosolutions, have already made forays into the bioinformatics industry. Recently, Ocimum was granted a patent for its method and system to manage and query gene expression data based on quality.¹⁰⁷

The Institute of Bioinformatics has also developed a comprehensive database of all known human proteins and their characteristics, and the Centre for DNA Fingerprinting and Diagnostics in Hyderabad along with Sun Microsystems has operationalised a Centre of Excellence focusing primarily on medical bioinformatics.¹⁰⁸ Some global pharma companies are already drawing on the emerging resources. Tata Consultancy Services has signed a deal with GSK to set up a support centre in Mumbai for the company's global drug development programme. Biocon has taken its tie-up with Bistol-Myers Squibb further by setting up a dedicated research facility, through its subsidiary Syngene International.

Stem cell research

Stem cells are seen by many as a powerful tool for improving the research and development process in the pharma industry. Stem cells are being used to develop some types of direct therapeutic applications; they are also becoming increasingly important as a tool to test potential drug toxicity.

India has already made considerable progress in this area. India's entry into stem cell research has progressed from a few institutions to currently over 40 institutions and hospitals involved in stem cell research.¹⁰⁹ In 2008, Stempeutics, a leading stem cell company, launched its second stem cell laboratory on the Manipal University campus for advanced stem cell research in human embryonic stem cells.¹¹⁰ Further activities followed in 2009 – one example is a joint venture formed by StemCyte in India with Apollo Hospitals and Cadila Pharmaceuticals to provide stem cell therapies.¹¹¹ Several major research institutes, such as the National Centre for Biological Sciences in Bangalore, the Centre for Cellular and Molecular Biology in Hyderabad, the National Centre for Cell Sciences in Pune and the National Brain Research Centre near Delhi, are investigating the use of stem cells to regenerate nerve,

heart and adult muscle cells, and repair damaged bone tissue. The L.V. Prasad Eye Institute has also treated blindness using stem cells derived from the eye.

While the Indian Government is strongly promoting biotech generally, concrete Government funding for stem cell research in India still lags far behind that provided in other countries such as the US. There are also no laws per se governing stem cell research, although there are specific guidelines which classify stem cell use into three categories: permissive, restricted, and prohibited. The Indian Council of Medical Research is currently drawing up plans for a national stem cell initiative to promote clinical applications of stem cell research in ophthalmology, cardiology and spinal cord repair, and build links between scientists and doctors. India's ex-president Dr. A.P.J. Abdul Kalam had also identified stem cell research as one of the areas on which the country should focus its efforts.

Given India's growing presence in biotech, drug discovery, and clinical testing, the country may be well positioned to take a leading role in leveraging the potential of stem cell technology throughout the pharma value chain.

The bottom line: India has made considerable progress in stem cell research and is well-positioned to leverage growing capabilities in this area.

The bottom line: Medical devices represent a significant potential market, however the sector currently lacks the regulatory and R&D support necessary to achieve its full potential and faces stiff competition from Europe and China.

Medical devices

Many pharmaceutical companies such as Bayer Healthcare, Johnson and Johnson Medical India (JJMI), Roche, and Piramal Healthcare are also looking to medical devices as a path to growth. The Indian medical devices and supplies market is at a nascent stage and was estimated at US\$2.75 billion in 2008. This is about 1.25% of the global medical devices and supplies market of around US\$220 billion in 2008. By 2012, India's medical devices market is expected to nearly double to around US\$5 billion.¹¹² Improving health infrastructure such as an increasing number of hospitals, clinics and clinical laboratories and telemedicine services are expected to drive demand. The production of low value medical supplies and disposables is dominated by domestic manufacturers, whereas the high end medical equipment is generally imported.¹¹³ The sector consists of the large medical-dental-surgical equipment segment which is about 50-60%, implantable devices which are around 20-30%, and simple plastic disposables which are around 20%.

The sector became regulated in 2005 under the Drugs and Cosmetics Act. The Ministry of Health and Family Welfare declared 10 products to be classified and listed as drugs under the Act. The list was expanded in March 2009 to include 19 more products. Under the Act, import registration requires product approval from another country's regulatory organisation such as the US FDA or the EU medical devices directive.¹¹⁴ The manufacture of any new type of a medical device is not covered under the Act and requires approval from an expert committee put together for the purpose.

In contrast to other biotech-related areas such as stem cell research and bioinformatics, the medical devices sector lacks the necessary regulatory and R&D support. Institutional support is also required for testing and validating facilities, as well as human resource development. In the future the industry is expected to face stricter regulation and competition from Europe as well as China.



Global Pharma's evolving business models and options in India

Background

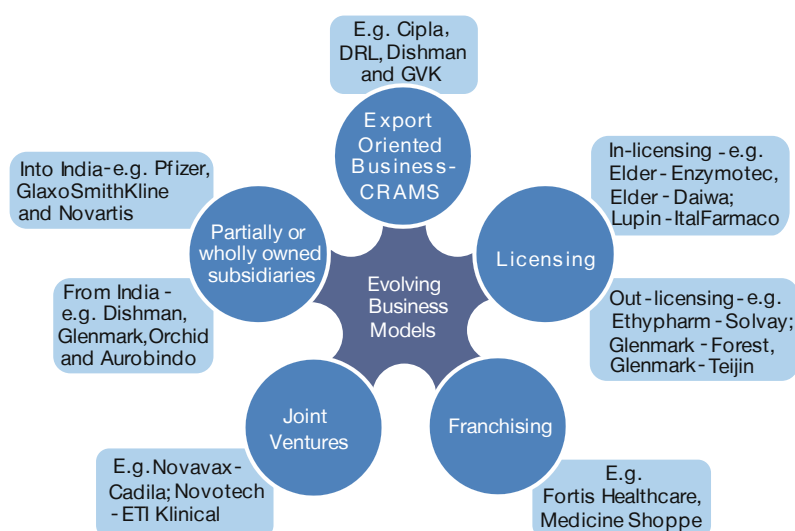
The global pharmaceutical industry is changing. In a report by PwC *Pharma 2020: Challenging business models*, we describe how the pharmaceutical business model is witnessing a paradigm shift from a fully integrated company structure towards a future where companies use a wide range of outsourcing, partnership initiatives and other contractual and relationship arrangements to create networks of collaboration and discovery. Eli Lilly, for example, is currently transforming itself from a traditional fully integrated pharmaceutical company into a fully integrated pharmaceutical network, in order to leverage on a wider range of resources beyond its physical boundaries. It aims to get better access to innovation, reduce its costs, manage its risks effectively and improve productivity.

This evolution in pharma business models has enormous repercussions for the Indian pharmaceutical sector, and related sectors like biotechnology. Indian companies now have an unprecedented opportunity to partner with global players across a wide range of activities, from contract manufacturing and licensing arrangements, to franchising and joint venture opportunities. The range of option spans a wide spectrum of levels of ownership and control, from straightforward outsourcing of manufacturing to licensing arrangements to more involved joint ventures and partially or wholly-owned subsidiaries (see **Figure 5**). The amount of investment risk varies accordingly.

Big Pharma is already well aware of India's importance. Many of them have been sourcing products from Indian manufacturers for some years, but have now started setting up their

The bottom line: Global pharma players can take advantage of a variety of options to maximise their investment in India. As many pharma companies turn to more collaborative business models, Indian companies are likely to play an increasingly important partnering role.

Figure 5 : Evolving business models



own production facilities. Sandoz, the generics arm of Novartis, has two manufacturing plants and a research centre for developing formulations and processes, based in Thane, near Mumbai. Pfizer also operates a manufacturing base in Thane. GSK has facilities based in Mumbai and Nashik; Apotex has a research centre and manufacturing plant in Bangalore; and Teva has an R&D centre in Greater Noida, having already bought a manufacturing operation in Uttar Pradesh in 2003. Mid-tier global pharma companies are present as well – Watson Pharma, Lonza, Eisai Pharmaceuticals, Ethypharm and Astellas all have manufacturing or research facilities in India. While their presence is certainly on the increase, only two foreign multinationals rank in the top 10 Indian companies, measured by sales – and even they only have 6.4% of the market between them (see Table 4).

Export-oriented business: CRAMS

Outsourcing has been the traditional method of doing business with Indian companies. Historically, the focus for the pharmaceutical industry has been on lower value add manufacturing activities such as APIs and generics, and India continues to play an important role in these segments.

Table 4: Only two foreign multinationals rank among the top 10 pharmaceutical companies in India

Major pharma company	Country sales, 12 months to Q4 2008, US(\$millions)	Country sales, 12 months to Q4 2007, US(\$millions)	Growth, 12 months to Q4 2008/2007, Fixed rate US\$(%)
Cipla	510	468	9.0%
Aurobindo	477	416	14.5%
Sun Pharmaceuticals	449	340	31.9%
Piramal Healthcare	428	354	20.9%
GSK	399	395	1.2%
Ranbaxy (Daiichi)	368	385	-4.5%
Cadila Healthcare	357	324	10.4%
Lupin	286	261	9.2%
Dr. Reddy's Laboratories	232	218	6.3%
Glenmark	134	146	-8.5%

Source: Annual Reports (2009) & Company Reports¹¹⁵

In recent years, India's pharma companies have also begun to move up the value chain. Foreign companies are now increasingly tapping India's growing research skills in addition to its manufacturing skills. Players such as Dishman and GVK-Biosciences undertake contract research for western companies. Low costs, availability of skilled talent and a large patient pool continue to be growth drivers for the CRAM segment in India. Ensuring that products and research comply with all relevant regulatory frameworks continues to be a challenge when

outsourcing to Indian pharmaceutical players, although the situation is improving.

Licensing

Multinationals are also striking licensing agreements to get a share of the Indian pie. For example, Elder Pharmaceuticals has entered into an exclusive in-licensing deal with Israel's Enzymotec to sell the latter's cholesterol-reducing dietary supplement, CardiaBeat, in India.¹¹⁶ Elder has also entered into another deal

with Daiwa Pharmaceutical of Japan to introduce Daiwa's nutraceuticals into the Indian markets.¹¹⁷ Lupin has in-licensed Lupenox, a cardiovascular drug from Italfarmaco, an Italian pharmaceutical company.¹¹⁸

In recent years, a wide array of out-licensing arrangements have also emerged. Ethypharm out-licensed and entered into a supply agreement for Mesalazine with Solvay Pharma.¹¹⁹ Glenmark has out-licensing deals with Forest, Teijin, Eli Lilly and Merck & Co.¹²⁰ Claris sealed a deal with Pfizer to license out 15 injectable generic medicines for pain, infections and other conditions.¹²¹

Most developmental costs are borne by the licensor in licensing arrangements, resulting in the licensee paying a high unit cost and having little control over manufacture. However, licensing can be effectively used to establish a common platform in order to gain rapid in-market acceptance and create a complete therapy range through arrangements such as cross-licensing.

Franchising

India's retailing industry also offers huge opportunities for foreign companies to either set up their own retail franchisee or enter into collaboration with existing players. Medicine Shoppe India,

the master franchisee of US-based Medicine Shoppe International has already forayed the market and plans to expand 1,000 stores by 2010.¹²² Fortis Healthcare plans to open a chain of 1,000 stores by 2012, of which the US\$200 million has been committed.¹²³ Franchising arrangements can leverage on purchasing power from the franchisor buying in large quantities and passing down savings to franchisees. Continued business support from the franchisor such as technology, products, training and marketing is an added advantage. However, there are restrictions on how the business must be managed in order to retain consistency among franchises. All franchisees are obligated to conform accurately to the initial business model.

Joint Ventures

Joint ventures (JVs) are becoming a more prevalent option for companies looking to capitalise on the opportunities presented in India. Foreign companies are increasingly looking at local partners to work with in order to increase their presence in India. Domestic partners bring together extensive local expertise due to their familiarity with the business environment, knowledge support and the networked capabilities of other local pharmaceutical companies. These advantages, along with low production

costs, skilled labor and faster drug development can be productively utilised by western pharmaceutical companies coming into India. As noted, India is home to more than 100 US FDA approved plants, so foreign companies looking for local partners can access a substantial manufacturing base.

R&D joint ventures are also growing in popularity. Some Indian companies are collaborating with overseas players to enhance their vaccine development capabilities, for example. Panacea Biotech has a joint venture with Chiron for development and marketing of vaccines.¹²⁴ Similarly, Novavax and Cadila Pharmaceuticals have a joint venture for the development and manufacture of vaccines and other biopharmaceutical products in India.¹²⁵

Other joint ventures focus on biotech or new biosimilars technologies. Novavax and Cadila Pharmaceuticals signed an agreement in March 2009 to form a joint venture, CPL Biologicals. CPL will develop and manufacture vaccines, biological therapeutics and diagnostics in India using technology contributed from Novavax and Cadila Pharmaceuticals.¹²⁶

Clinical testing also offers opportunities. In 2009 Novotech, an Australia based clinical research company, entered into a strategic venture with ETI Klinical to service the growing demand for

Requirements of a JV

Foreign companies forming a joint venture in India require Government permission. These are regulated as domestic companies. However, the approving authority depends on the sector funds are invested in and the route of investment – automatic or otherwise. Investments made in joint ventures via the automatic route require the approval of the Reserve Bank of India. Other cases require prior approval from the Foreign Investment Promotion Board (FIPB). The FIPB is empowered to provide complete clearance for such cases. The Secretariat for Industrial Assistance (SIA) processes all applications requiring FIPB approval.

The Government has designated 35 high priority areas where foreign participation is pre-approved, including pharmaceuticals. These industries have sector wise limits for automatic approvals. The RBI usually grants automatic approvals within two weeks of filing applications.

clinical research and clinical and data management services in India.¹²⁷ Joint ventures offer many ways for partners to pool their Intellectual Property (IP) and to share risks and rewards equally. These types of arrangements can be particularly attractive to biotechnology or national pharmaceutical companies who wish to retain some control over development and to sell the resulting product in some markets, but who lack the ability to undertake global development and commercialisation. However, the profit and/or sales split may be determined as much by the companies' relative market strengths as by the value of their initial IP.

Partially or Wholly owned subsidiaries

Some multinational companies have also increased their stake in their Indian subsidiaries to take advantage of the India opportunity. Pfizer has been able to increase its stake in its Indian arm, Pfizer India, from 41.2% to around 72%.¹²⁸ Similarly, Novartis AG has

hiked its stake to 76.42% in its Indian subsidiary Novartis India from 50.9%.¹²⁹ Other companies are using local subsidiaries to set up their own sales and marketing organisations, either organically or through acquisitions. GSK has headquartered its wholly-owned subsidiary SB Asia in India. Novartis has two wholly owned companies in India – Novartis Consumer Health Private Limited and Sandoz India Private Limited. Pharmacia India Private Limited remained as a wholly owned subsidiary and was not consolidated with Pfizer India during Pfizer's acquisition of Pharmacia.¹³⁰

Unlike in some other sectors, fully owned subsidiaries in the pharmaceutical industry offer little risk in terms of sharing critical data and competitive advantage, as most are subject to strong control by the parent company. Pharmaceutical companies willing to have wholly owned operations in India can gain value from being present across the value chain, from drug discovery to clinical trials through to manufacturing. Other benefits may include tax advantages.



Practical concerns

Infrastructure

Insufficient energy infrastructure and inadequate transport infrastructure has historically posed challenges for companies operating in India. The situation is definitely improving, as the Government focuses attention on infrastructure needs. The Indian infrastructure sector continues to be viewed as an investment opportunity, despite the global slowdown.

In early 2009, the Indian Government was reported to be mulling over a plan to use part of its foreign exchange reserves to fund certain forms of infrastructure spending. It is also keen to encourage public-private partnerships (PPPs) in infrastructure development projects. The Union Ministry of Health and Family Welfare, along with the pharmaceutical industry and airport developers GVK and GMR, plan to set up dedicated cargo zones to handle the import and export of pharma products.¹³¹ Such initiatives could spur substantial improvements in India's infrastructure over the medium-term.

Tax environment

India is expected to implement a new Direct Tax Code, pending approval, by April 2011, which should simplify the existing tax structure. The new tax code proposes a reduction in the corporate tax rate from the current 30% to 25% and an unlimited carry forward of business losses. A dual system GST has also been proposed for April 2010. The implementation of the new GST may face delays. The new system

would impose taxes at both federal and state levels and differentiate between goods and services. The new dual GST is designed to aggregate different indirect taxes currently levied, in order to simplify and integrate the current system of indirect taxation.

India already offers a variety of tax concessions to the pharmaceutical sector, including tax holidays for industrial operations established in free trade zones or under-developed areas; deduction of profits earned from exports; liberal depreciation allowances; deduction of capital R&D expenditure; and relief on all contributions to approved domestic research institutions. For pharma manufacturing units, there is an additional weighted deduction of 200% for expenditures relating to in-house R&D.¹³² Further, recently, a new provision has been added to provide 125% weighted deduction for expenditure incurred towards outsourcing of R&D activities.

At present, foreign direct investment in manufacture of drugs and pharmaceuticals including those involving use of recombinant DNA technology is freely permitted up to 100% under the automatic route, i.e., without obtaining any prior regulatory approval.

Of particular interest for pharma companies may be the special economic zones (SEZs). In order to incentivise the country's export sector, the Government has formulated the SEZ policy, which offers cost and tax benefits. On the corporate tax front, units set up in SEZs enjoy 100%

The bottom line: India offers some attractive tax benefits for pharma companies and reductions in customs duties should also help global manufacturers compete in the price-sensitive Indian market.

income tax exemption on export profits in the first five years of operation, 50% exemption for the next five years, and 50% exemption on the reinvested export profits in the following five years. Companies located in SEZ also benefit from various Indirect Tax benefits such as exemption from payment of Customs Duty; Excise Duty; Central Sales Tax and refund and exemption of Service Tax.

Currently, SEZs must adhere to a positive net foreign exchange obligation policy (i.e. where the total value of exports should be more than the total value of imports) under the Import Export policy, in order to retain SEZ status. A proposal has been made to exempt pharma SEZs from this requirement.¹³³

In an effort to attract companies to SEZs, some of these are located in modern industrial areas. The Jawaharlal Nehru Pharma City, India's first and largest pharma industrial estate, includes a SEZ. The facility is located near Visakhapatnam, in close proximity to many chemical manufacturing hubs, and offers common infrastructure for resident pharma companies. There are three other pharma SEZs

located in Andhra Pradesh, and four in Maharashtra, as well as one on the outskirts of Dehra Dun in Uttarakhand, so global pharma companies have a range of options.

At this stage, it may also be pertinent to note that the draft Direct Tax Code Bill published by the Government presently does not provide for SEZ-related incentive schemes. However, recent press releases suggest that the Finance Minister has identified proposed incentive provisions as one of the areas for detailed examination prior to finalisation of the Direct Tax Code.¹³⁴

Overall, India offers a favourable environment as far as taxation policies for pharmaceuticals are concerned. In addition to the attractive tax benefits for companies pursuing innovative R&D in India, the recent budget 2010-11 has provided certain benefits to pharmaceutical industry. In this budget, a uniform, concessional basic duty of 5%, countervailing duty (CVD) of 4% with full exemption from special additional duty has been prescribed on all medical equipment, while the parts and accessories for manufacture of these equipment has been prescribed only the basic custom duty of 5%

and exempted from CVD and special additional duty. Specified inputs of orthopaedic implants and medical equipment and devices such as assistive devices, rehabilitation aids, etc. are fully exempted from import duty.¹³⁵ The 2009-10 budget reduced the customs duty on import of influenza vaccine and nine specific life saving drugs and bulk drugs used for the manufacture of such drugs to 5%. This will better enable foreign drug-makers to sell products at a lower price point and better compete in India's highly price sensitive market.

Counterfeiting

Counterfeit drugs have been a serious issue in India. The Organisation of Pharmaceutical Producers of India (OPPI) has spearheaded various initiatives to combat the problem. It has conducted several seminars and worked closely with the Ministry of Health to develop policies for controlling the production and sale of 'spurious' drugs. It has also published a series of anti-counterfeiting guidelines for the industry as a whole. Surprisingly, a recent nationwide survey conducted by the health ministry, published in December 2009 finds a much lower incidence of spurious drugs in the country than

previous industry estimates. It found the prevalence of spurious drugs at 0.046% of all medicines sold to customers, in contrast to results of an earlier survey funded by the WHO and undertaken by the International Pharmaceutical Federation, which concluded that 3.1% of drugs in India were counterfeit.¹³⁶ While such findings are a positive sign, companies should remain alert to possible counterfeiting issues.

Intellectual Property Rights

The federal Government introduced product patents for all industrial sectors under the Patents (Amendment) Act, 2005 – in line with the commitment India made when it signed up to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Accord in 1995. This regulation aims to balance the interests of domestic and multinational drug makers. It represents a major improvement on the previous rules, but some issues remain. Firstly, it does not apply to drugs patented before 1995.¹³⁷ Copies of drugs patented between 1995 and the introduction of the law will probably not be withdrawn.

The Ordinance also allows third parties to oppose an application for a patent,

which will prolong the period required to issue a grant. It permits compulsory licensing in some circumstances other than national emergencies and public health crises – provisions that could be abused for commercial gain.

Further, patent rights for ‘mail box’ applications filed will only accrue from the date the patent is granted.¹³⁸ Lengthy delays are common, as the Indian Patent Office lacks sufficient resources to process applications very rapidly. While a ‘mail box’ application is pending, generic manufacturers can freely produce the same drug without fear of incurring any liability for damages.

Post 2005 India has made several amendments to better protect intellectual property rights and enable global pharma companies to bring their patented products to India, while protecting the interest of home grown companies. The Satwant Reddy committee’s report on data protection has recommended pro-patent amendments and data exclusivity for a period of five years.¹³⁹ The enforcement regime is also changing, but the legal system is currently too overburdened for these improvements to be immediately effective.

In December 2008, the Delhi High Court’s landmark judgment in favor of Bristol-Myers Squibb, the patent holder for the leukemia drug Dasatinib, restrained Hetero Drugs from manufacturing and marketing generic versions of the drug. In the past, marketing approvals were sometimes granted by the DCGI independently of the patent status of the drug in question. The judgment establishes a link between patent and marketing approvals granted by the IPR office and the DCGI.¹⁴⁰

In June 2009, Novartis’ cancer drug Glivec was not awarded a patent for lack of improved efficacy under section 3(d) of the Indian Patent Act and its high price as ruled by the Intellectual Property Appellate Board (IPAB).¹⁴¹ The former justification has since come under scrutiny. In August 2009, the Government accepted the recommendations of the Mashelkar committee supporting patenting of incremental innovation. The Mashelkar report also pointed that efforts were required to provide drugs at affordable prices to the people of India and to prevent the granting of frivolous patents and evergreening.

Conclusion

The Indian market is impossible to ignore, given its economic prospects. Foreign companies view India as a potential significant contributor of future sales and are ramping up their investments in the country accordingly. India's domestic market looks promising for global pharma looking to launch new products. The country's growing capabilities in contract manufacturing, R&D and clinical trials also make it a preferred outsourcing partner for global pharma at every stage of the value chain. So what strategy should foreign pharmaceutical companies eager to enter the country or expand their existing operations adopt?

One approach is to call on India's increasing expertise in biotechnology, bioinformatics and clinical testing. Several overseas companies have outsourced research and clinical trials to Indian contractors, while others have entered into collaborative R&D arrangements to supplement their R&D productivity. Many foreign companies have also already initiated research on neglected diseases. We believe that many more will do so, as the patent regime is strengthening. This will enable them to capitalise on the cost savings to be gained from shifting some research activities to India, without jeopardising their most valuable intellectual property.

Another approach is to tap into the growing domestic market. Foreign companies with a product portfolio spanning across different therapeutics segments can look at bringing newer products in India by entering into collaborative networks across the value chain, from sourcing and manufacturing to marketing and distribution. These companies will have to understand how to get their product to market and develop a realistic pricing strategy, particularly as India is still far away from a widespread shift to an insured payer model.

India's pharma market is highly fragmented and remains extremely price sensitive. Affordable healthcare continues to pose a challenge, although there are a number of healthcare initiatives by the Government underway to improve the situation for India's vast population. Indian courts and regulatory authorities are very sensitive to pricing issues in making decisions around intellectual property. Pharma companies coming into India may need to consider a differential pricing. They will need to evaluate access to medicines, a volume-based pricing strategy and take into account gradually increasing per capita incomes to come up with acceptable price levels for their drugs. Global pharma companies will then need to decide how to manufacture their products, and identify and develop strong local partners.

One way to build a presence in India may be through an increased presence in the OTC market. Promoting a range of OTC products could serve as means of building brand awareness and as a source of new revenues. Indigenous producers dominate the generics business, and about 97% of all drugs sold in India are already off patent. The OTC market is, by contrast, relatively undeveloped. Indian consumers already pay privately for the lion's share of their healthcare, and the Government is too hampered by budgetary constraints to reverse this pattern. In future, then, it seems likely that access to OTC medicines will be improved and the market will continue to expand.

The pharmaceutical business model is witnessing a paradigm shift, moving from a fully integrated company structure towards a future where companies use a wide range of outsourcing, partnership initiatives and other contractual and relationship arrangements to create networks of

collaboration and discovery. Investing in India will be a vital component of this networked future. Companies that will be most successful in doing business in India will be those that are most adept at managing and mixing a range of contractual relationships and partnership strategies.

Some practical issues will need to be addressed, regardless of the business model selected. Infrastructure deficits continue to exist, although some are being addressed. Intellectual property protection has improved substantially but some holes remain. And while the regulatory environment in India has improved substantially in recent years, the industry still faces a number of question marks. Finalisation of Government policies around drug price control, access to OTC drugs, tax policy, intellectual property protection and infrastructure spending is still pending.

Nonetheless, India's appeal is growing rapidly in a number of respects. It has long been a formidable player in pharmaceutical manufacturing, but its socio-economic strengths provide even greater grounds for optimism. If the economy outpaces that of every other emerging country for the next half century, as many commentators expect, large portions of the population will be able to afford modern medicines. India's increasing scientific expertise will also equip it to play a significant role in researching and developing those drugs. It has a large pool of highly educated, English speaking scientists who can undertake research and conduct trials more cheaply and in some cases faster than their Western peers. These are major advantages in a world where drug development costs are soaring and getting to market fast is vital.

Related reading

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Fourth in the series, the report explains why Pharma's fully integrated business models may not be the best option for the pharma industry in 2020 and why more creative collaboration models may be more attractive. The paper also evaluates the advantages and disadvantages of the alternative business models and how each stands up against the challenges facing the industry.

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Acronyms

ANDA - Abbreviated New Drug Application	GSK - GlaxoSmithKline
API - Active Pharmaceutical Ingredient	GST - Goods and Sales Tax
BCG - Bacille Calmette-Guérin	hGH - Human Growth Hormone
BIPP - Biotechnology Industry Partnership Programme	IP - Intellectual Property
BPL - Below Poverty Line	IPAB - Intellectual Property Appellate Board
CAGR - Compounded Annual Growth Rate	IRDA - Insurance Regulatory and Development Authority
CRAMS - Contract Research & Manufacturing Services	JJMI - Johnson and Johnson Medical India
CROs - Contract Research Organisations	JVs - Joint ventures
CVD - Countervailing Duty	NPPA - National Pharmaceutical Pricing Authority
DBT - Department of Biotechnology	NREGA - National Rural Employment Guarantee Act
DCGI - Drug Controller General of India	NRHM - National Rural Health Mission
DPCO - Drug Price Control Order	OPPI - Organisation of Pharmaceutical Producers of India
DPT - Diphtheria, Pertussis or Whooping Cough, and Tetanus	OTC - Over The Counter
DRL - Dr. Reddy's Laboratories	PE - Private Equity
EMA - European Medicines Agency	PPPs - Public-Private Partnerships
EU - European Union	PwC - PricewaterhouseCoopers
FCCBs - Foreign Currency Convertible Bonds	R&D - Research and Development
FDA - Food and Drug Administration	RBI - Reserve Bank of India
FDI - Foreign Direct Investment	SEZs - Special Economic Zones
FIPB - Foreign Investment Promotion Board	SIA - Secretariat for Industrial Assistance
GCSF - Granulocyte Colony Stimulating Factor	TRIPS - Trade Related Aspects of Intellectual Property Rights
GIC - General Insurance Company	WHO - World Health Organisation
GLP - Good Laboratory Practices	

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